



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,514	06/05/2001	Samuel J. Danishefsky	2003080-0082 (SK-744-CON3)	6697

24280 7590 04/16/2002

Choate, Hall & Stewart  
Exchange Place  
53 State Street  
Boston, MA 02109

EXAMINER
----------

SOLOLA, TAOFIQ A

ART UNIT	PAPER NUMBER
----------	--------------

1626

DATE MAILED: 04/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/874,514**

Applicant(s)  
**Danishefsky et al.**

Examiner  
**Taofiq A. Solola**

Art Unit  
**1626**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 14, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 30 and 59-94 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30 and 59-94 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8 20) ☐ Other:

Art Unit: 1626

Claims 30, 59-94 are pending in this application.

Claims 1-29, 31-58 are canceled.

***Claim Renumbering***

The amendment filed 2/14/02 canceled claims 1-29 and 31-59, and added new claims 60-63 and 65-96. Claims 59 and 64 were not filed. Therefore, under Rule 126, the Docket Clerk in charge of this application has renumbered the new claims 60-63 and 65-96, as 59-94.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30, 59-94, are rejected under 35 U.S.C. 103(a) as being unpatentable over Bollag et al., Cancer Res., Vol. 55 (1995), pages 2325-2333.

Applicants claim composition of epothilone and methods of use for treating cancer or tumors particularly drug-resistant cells. In preferred embodiments, the composition further comprises at least one cytotoxic agent. Applicants also claim effective amounts of epothilones from about 0.001 to about 1 mg/kg of body weight.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Art Unit: 1626

Bollag et al., teach epothilones A and B, their compositions as oily residue (column 2, page 2326) and methods of use for treating cancer or tumor cells and particularly multiple drug-resistant cells. See column 2, page 2331. Bollag et al., also teach the method of use of epothilones in combination with taxol (a cytotoxic agent). See column 2, page 2328 to column 1, page 2330.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Bollag et al., is that applicants are claiming effective amounts of epothilones from about 0.001 to about 1 mg/kg of body weight.

Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)

However, for Bollag et al., to use epothilones for the treatment of cancer or tumors, effective amount must necessarily be used. Also, claiming effective amounts of epothilones from about 0.001 to about 1 mg/kg of body weight, is not in and of itself patentable over the prior art of Bollag et al. Therefore, the instant invention is prima facie obvious from the teaching(s) of Bollag et al. The motivation is to make additional epothilone composition useful for the treatment of cancer.

***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg.*

Art Unit: 1626

*Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 30, 59-94, are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 59-95 of copending Application No. 10/058,695. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Objection***

Claims 59 and 69 are objected to because they are duplicates. Both claims are drawn to a composition which of the same structural formula and a pharmaceutically acceptable carrier. By deleting one of the claims the rejection would be overcome.

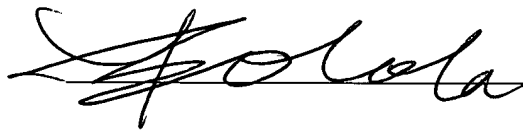
### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Taofiq A. Solola whose telephone number is (703) 308-4690. The examiner is on flexible work schedule and the best days to get him are Mondays, Wednesdays and Fridays.

Art Unit: 1626

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Taofiq A. Solola', written over a horizontal line.

Taofiq A. Solola, Ph.D.

Primary Examiner

Group 1626

April 12, 2002